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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,335	12/21/2001	Sivaram Pillarisetti	18631-0121 (45115-264494)	1157
26158	7590	01/10/2006	EXAMINER	
WOMBLE CARLYLE SANDRIDGE & RICE, PLLC P.O. BOX 7037 ATLANTA, GA 30357-0037			SAUNDERS, DAVID A	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/026,335

Applicant(s)

PILLARISSETTI ET AL.

Examiner

David A. Saunders, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/30/05 and 10/17/05.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-14 and 16-34 is/are pending in the application.
- 4a) Of the above claim(s) 8, 9 and 16-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 10-14 and 16-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/21/03 WITH CORRECTION ENTERED
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Amendments of 6/30/05 and 10/17/05 have been entered. Claims 1-6, 8-14 and 16-34 are pending. Claims 1-6, 10-14 and 27-34 are under examination.

The amendment has overcome previously stated issues as follows:

The objection to the specification.

The objection to claims 4, 10 and 13 for informalities.

The rejection of claims 1-6, 10-14 and 27-34 under 35 USC 112, 2nd paragraph.

The rejection of claims 1-6, 10-14 and 27-34 under 35 USC 112, 1st paragraph, as set forth at page 5 of the action mailed 3/25/05.

The prior art rejection based upon Bian et al; the experiments discussed in the para. spanning pp 67-68 and in Table 2 do not use cells within the scope of the claims.

The prior art rejection based upon Yan et al; the neuroblastoma cells used by Yan et al are not within the scope of the instant claims.

Applicant's amendment has necessitated the following modifications of old grounds of rejection and/or a statement of new ground(s) of objection/rejection.

Claims 1 and 27 are objected to because of the following informalities: In the text added to steps b) and d) of claim 1, "determinate" should be -determinant--. In the text added to step d) of claim 27, "determinate" should be -determinant--. Appropriate correction is required.

Claims 10-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the preamble of claim 10 the phrase "that affect glycosylated protein" is indefinite because one does not know what kind of "effect" is to be determined; likewise, in step d), the terms "a stimulating effect, an inhibitory effect, a stabilizing effect, or no effect" are indefinite because one does not know what "effect" is being stimulated, inhibited, or stabilized. Is one considering the synthesis of glycosylated protein, or the degradation thereof? Is one considering some "effect" that the glycosylated protein has upon some other biochemical component of cells?

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The claim is further confusing because the preamble and step d) call for determining something that affects glycated protein per se, while steps a)-c) appear to determine an effect that glycated protein has upon cells in culture.

Claims 1-6, 10-14 and 27-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Step c) of claims 1, 10 and 27 contains new matter by reciting “vascular and/or aortic endothelial cells”. Applicant has recited the genus of “endothelial cells” at pages 9-11. Applicant has recited the species of “human aortic endothelial cells” (HAEC) and “microvascular endothelial cells” (HMVEC) at page 14; the “H” in “HMVEC” is taken as referring to cells of human origin. These species do not support the subgenus of “vascular endothelial cells” or the subgenus of “aortic endothelial cells” because each subgenus is not limited to cells of human origin. Also, the examiner finds nothing in the examples where the HAECs and the HMVECs were explicitly disclosed as being co-cultured; thus recitation of “and” within “and/or” constitutes new matter.

Claims 10-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 14 recites new matter. As noted supra under 112, second para., one does not know what kind of “effect” upon glycated protein is being determined. The claims thus encompasses more than was originally claimed or shown anywhere in the original disclosure.

Claims 10-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The method of claim 10

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does not enable the detecting of “compositions that affect glycated protein”. As noted supra, under 112, second para., the examiner considers that steps a)-c) determine an effect of glycated protein upon cultured cells, but nothing determines any “effect” upon glycated protein per se.

Claims 1, 4, 27-29 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Medford et al (5,846,959, previously cited as of interest).

Medford et al teach methods in which HAECs or HUVECs are treated with a stimulatory agent. The stimulatory agent can be a polyunsaturated fatty acid (PUFA) or the hydroperoxide (ox-PUFA) derivative thereof. The stimulatory agent can also be TNF-alpha. Following such stimulation the treated cells show increased cell surface expression of VCAM-1 as a determinant of inflammation. Prior treatment of the stimulated cells with a dithiocarbamate/dithiocarboxylate, such as PDTC, can inhibit the effect of the stimulatory agent. See, for example, col. 13, lines 25-42; col. 21, lines 15-28; col. 23, line 62-col. 24, line 54. With respect to the instant claim limitation that the component of step a) has “an unknown effect upon inflammation”, note that Medford et al teach that the effects of particular dithiocarbamate/dithiocarboxylate compounds should be evaluated with respect to their ability to affect VCAM-1 expression; see col. 15, lines 40-60 and col. 19, lines 53-65. Claims 4 and 27 are thus anticipated, or at the least, would have been obvious.

Dependent claims 4 and 28 are rejected because any dithiocarbamate/ dithiocarboxylate of the reference is a “compound” or a “molecule” or a “pharmacological agent” (e.g. col. 15, lines 38-col. 16, line 49).

Dependent claim 29 is rejected because Medford et al disclose treatment of various recited diseases with the dithiocarbamate/dithiocarboxylate compounds. See col. 3, line 61-col. 4, line 6 and col. 34, lines 11-32.

Dependent claim 32 is rejected because Medford et al culture the cells for a predetermined amount of time after adding the stimulatory agent (e.g. see col. 13, lines 30-35).

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains claims 8-9 and 16-26 drawn to an invention nonelected with traverse in the Paper filed 12/6/04. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, PhD whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 1/4/06 DAS

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182-1644